

The opinion in support of the decision being entered today  
is *not* binding precedent of the Board.

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* BRIAN A. TOROK, RAMADA S. SMTIH  
and VALERIE RICE-MONTGOMERY

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Appeal 2007-2405  
Application 09/758,978  
Technology Center 3700

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Decided: September 12, 2007

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Before DONALD E. ADAMS, ERIC GRIMES, and NANCY J.  
LINCK, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to a method for identifying premature membrane rupture during pregnancy. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## BACKGROUND

The Specification describes “an article for the identification of the premature rupture of a membrane during pregnancy . . . in the form of a multilayered pad that is fitted to the undergarment of a user. The multilayered pad includes a treated component which responds to the presence of amniotic fluid as a discharge.” (Substitute Specification 1.) Specifically, the Specification describes “an indicating device that comprises . . . a pad having an upper outer layer, a lower outer layer, and an intermediate pH-responsive layer” (*id.* at 6).

Alternatively, the Specification describes selectively placing a pH-sensitive liquid on a feminine pad and wearing the pad in its usual manner (*id.* at 8). The Specification also states that the “pH-sensitive material . . . may be applied to the pad or other article . . . in the form of liquid drops, an atomized spray . . . , a sprayed liquid (which may be from an aerosol or pump spray container), a powder, a sheet or solid pH-sensitive material . . . , or a gel material” (*id.* at 20).

## DISCUSSION

### 1. CLAIMS

Claims 2-5, 7-11, 13-16, and 31-34 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 2, which is representative and reads as follows:

2. A method for use by a pregnant woman for identifying the premature rupture of a membrane during pregnancy, the method comprising the sequential steps of:

forming an article for wearing substantially adjacent the crotch of the pregnant woman;

applying to said article a pH-sensitive material capable of responding by way of a visible change to the presence of a fluid with a pH in the range of amniotic fluid, said pH-sensitive material being non-irritating to the woman and having a readily applicable form, said form being selected from the group consisting of liquid drops, atomized spray, aerosol liquid, powder, gel, and a solid;

wearing said article for a period of time; and

visualizing said pH-sensitive material for a visible change.

Thus, claim 2 is directed to method for identifying premature membrane rupture during pregnancy. The method comprises forming an article; applying a pH-sensitive material to the article; wearing the article; and looking for a visible change in the pH-sensitive material. We interpret claim 2 to require that a pH-sensitive material be applied to an article, but based on the comprising language, we interpret claim 2 to encompass methods in which an additional layer of material is applied over the pH-sensitive material.

## 2. PRIOR ART

The Examiner relies on the following reference:

Yazaki

JP-5-123324

May 21, 1993

### 3. ANTICIPATION

Claims 2-5, 7-11, 13-16, and 31-34 stand rejected under 35 U.S.C. § 102<sup>1</sup> as anticipated by Yazaki. The Examiner finds that Yazaki

shows a pad wearable “substantially adjacent the crotch” of a women that has a color indicator that changes color in the presence of amniotic fluid and teaches the method for detecting rupture of the amniotic membrane, including premature rupture[,] by wearing the pad, and looking at the pad for a period of time to detect a color change of the indicator.

(Answer 4.)

We conclude that the Examiner has set forth a prima facie case of anticipation. Yazaki describes a pad for determining rupture of the amniotic sac, which is installed by a pregnant woman in the same manner as a sanitary pad (Yazaki 2 and 4). The pad is equipped with a pH indicator sheet having an impregnatable sheet portion impregnated with bromthymol blue, which changes color when it contacts amniotic fluid (*id.* at 4). Yazaki describes manufacturing the pad by encasing an absorptive member with nonwoven fabric, aligning the pH indicator sheet with the nonwoven fabric, and compressing the assembly with a press roller. The assembly is then encased in laminated paper so that only the pH indicator sheet portion remains exposed, is encased in nonwoven fabric, and is heat sealed. (*Id.* at 6.)

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<sup>1</sup> The Examiner’s Answer states that this rejection is under 35 U.S.C. § 102(e). However, Yazaki is a published Japanese patent document and does not qualify as prior art under § 102(e), although it does qualify as prior art under § 102(b). Thus, this rejection is being treated as a rejection under § 102(b).

Appellants argue that “Yazaki does not show that which is claimed” (Br. 8). In Yazaki, the “pH indication agent sheet is disposed *within* the pad (*id.*). Specifically, the pH indication agent “sheet 6 is placed underneath the unwoven cloth 5 and will not and cannot be brought into contact with the skin of the wearer” (Br. 9 (emphasis omitted)). Thus, Appellants argue that Yazaki does not teach the embodiment depicted in Appellants’ Figure 6, which is purported to be claimed (*id.*).

We are not persuaded by this argument. First, claim 2 is not limited to the embodiment depicted in Appellants’ Figure 6. As discussed above, we conclude that claim 2 encompasses methods in which an additional layer of material is applied over the pH-sensitive material. Thus, we do not agree that claim 2 excludes a pH indication agent disposed within a pad.

In addition, we agree with the Examiner that the language of claim 2 does not require that the pH-sensitive material be brought into direct contact with the skin of the wearer (Answer 5). Instead, claim 2 states that the article is for wearing substantially adjacent the crotch of a pregnant woman. Yazaki describes a pregnant woman wearing the pad in the same manner as a sanitary pad (Yazaki 2 and 4). Thus, Yazaki describes wearing the pad, including the portion of the pad to which the pH indicator is applied, substantially adjacent the crotch of a pregnant woman.

Appellants also argue that, “[b]y using a non-irritating pH indicator, the present invention is patentably different from Yazaki” (Br. 11). In support of this position, the Appeal Brief refers to evidence that was attached to the Appeal Brief (*id.*). Appellants also request that “the Board

take official notice of the known and readily-ascertainable fact that bromothymol blue is a skin irritant” (Reply Br. 2-3).

We are not persuaded by this argument. First, we decline to take official notice that bromothymol blue is a skin irritant. Official notice is appropriate only when “the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known.” Manual of Patent Examining Procedure § 2144.03. The status of bromothymol blue as a skin irritant is not a fact that is unquestionably well-known.

Second, we agree with the Examiner that the evidence that was newly presented by Appellants with the Appeal Brief was properly denied entry. Such evidence is properly admitted only if the “the examiner determines that the . . . evidence overcomes all rejections under appeal and that a showing of good and sufficient reasons why the . . . evidence is necessary and was not earlier presented has been made.” 37 C.F.R. § 41.33(d)(1). Here, the Examiner has determined that “there is no showing of good and sufficient reason why the evidence was not previously submitted” (Answer 5). Thus, we agree with the Examiner that “the record on appeal is . . . devoid of any evidence establishing that bromothymol blue is a skin irritant” (*id.*).

#### SUMMARY

We conclude that the Examiner has set forth a *prima facie* case that claim 2 is anticipated by Yazaki, which Appellants have not rebutted. We therefore affirm the rejection of claim 2 under 35 U.S.C. § 102. Claims 3-5, 7-11, 13-16, and 31-34 fall with claim 2.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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